IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **ALL PLAINTIFFS LISTED IN PLAINTIFFS' MOTION**	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE OR LIMIT THE OPINIONS AND TESTIMONY OF SALIL KHANDWALA, M.D.

Salil Khandwala, M.D. is board-certified in Obstetrics and Gynecology, with a subspecialty board certification in Female Pelvic Medicine and Reconstructive Surgery. Ex. B to Pls.' Mot. (Dkt. 2003-2), Khandwala Report at 2; *see also* Ex. 1, Khandwala CV. He is the Director of Female Pelvic Medicine and Reconstructive Surgery at Beaumont Hospital. *Id.* He has participated in both the Urinary Incontinence Treatment Network and the Pelvic Floor Disorders Network, two robust clinical trial groups. *Id*. Dr. Khandwala has used mesh in more than 1,000 stress urinary incontinence procedures and in over 800 prolapse procedures. *Id*. at 2-3. Throughout his career, Dr. Khandwala has managed complications related to pelvic floor surgeries including those associated with native-tissue repairs, sacralcolpopexies, and transvaginal mesh procedures. *Id*. at 3. And he has conducted studies relating to pelvic reconstructive surgery, both as the principal investigator and as a participant. *Id*.

Despite these credentials and extensive experience, Plaintiffs seek to exclude Dr. Khandwala's opinions regarding: (1) the safety and efficacy of the Prolift and Prolift+M; (2) comparisons between mesh and nonmesh pelvic organ prolapse procedures; (3) biomaterials,

biocompatibility, and mesh physical properties (*i.e*. contraction, degradation, porosity and stiffness); and (4) Instructions for Use (IFU). Plaintiffs' motion should be denied because:

- **Dr. Khandwala's safety and efficacy opinions are based on reliable methodology**. Plaintiffs do not address the bases for Dr. Khandwala's safety and efficacy opinions. They instead criticize his selection and interpretation of literature to support his opinions concerning success rates between mesh and nonmesh repairs. The alleged flaws go to the weight of the evidence, not its admissibility.

- **Dr. Khandwala is qualified to opine concerning the physical properties and biocompatibility of the Prolift devices**. This Court has held on several occasions that surgeons are qualified to opine on mesh properties and biocompatibility despite lack of specific expertise in biomaterials and pathology.

- **Dr. Khandwala's opinions on mesh contraction are reliable under *Daubert*.** Dr. Khandwala supports these opinions with his surgical experience, analysis of the literature, and clinical trial data demonstrating the effect of contraction (vaginal shortening) does not occur.

- **Dr. Khandwala's comments on porosity and stiffness support his opinions regarding surgeons' understanding of the Prolift devices' physical characteristics and differences.** Plaintiffs take these comments out of context.

- **Dr. Khandwala does not intend to opine on the Instructions for Use or degradation.**

Plaintiffs' challenges to Dr. Khandwala's opinion testimony are meritless under Rule 702 and *Daubert v. Merrell Dow Pharm., Inc*., 509 U.S. 579 (1993). Defendants Ethicon, Inc. and Johnson & Johnson (Ethicon) therefore ask that Plaintiffs' motion be denied.

ARGUMENTS AND AUTHORITIES

I. Plaintiffs' Motion Should Be Denied Because Dr. Khandwala's Safety and Efficacy Opinions are Based on Reliable Information and Data.

A. Plaintiffs Overreach in Their Request to Exclude Opinions Beyond Those They Address in Their Motion.

While Plaintiffs ask the Court to exclude all of Dr. Khandwala's "opinions on safety and efficacy," their criticisms focus on Dr. Khandwala's opinions on success rates between mesh and nonmesh prolapse procedures. Pls.' Mem. (Dkt. 2004) at 3. Yet these opinions, while important, do not form the basis for his opinion that the Prolift devices are safe and effective. Rather, as Dr. Khandwala's expert report and deposition explain, he relies upon his analysis of the medical literature, his experience in several clinical trials, his discussions with other surgeons at meetings, and his experience as a surgeon implanting over 1000 midurethral slings, performing 800 pelvic organ prolapse mesh procedures, and treating complications experienced by his own and other surgeons' patients. *See* Ex. B to Pls.' Mot. (Dkt. 2003-2), Khandwala Report at 2-4, 8, 12-16.; Ex. C Pls.' Mot. (Dkt. 2003-3), 3/25/16 Khandwala Dep. Tr. 131:9-132:5, 170:11-172:11.

This background has been found to be a sufficient basis under *Daubert* to render safety and efficacy opinions. *See, e.g.*, *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 714 (S.D.W. Va. 2014) (A physician's "knowledge, experience, and review of scientific literature provide sufficiently reliable bases for his opinions under Daubert."); *Mathison v. Boston Scientific Corp.*, No. 2:13-CV-05851, 2015 WL 2124991, at *29 (S.D.W. Va. May 6, 2015) (same); *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *7 (S.D.W. Va. Apr. 24, 2015) (same); *see also Berg v. Johnson & Johnson*, 940 F. Supp. 2d 983, 998 (D. S.D. 2013) (finding opinions based on expertise in the field, expert's past research, and

published studies reliable; any gaps or limitations in the expert's reasoning can be presented to the jury). Thus, the Court should disregard Plaintiffs' overreaching request to exclude all of Dr. Khandwala's safety and efficacy opinions, focusing instead on the mesh versus nonmesh success rate opinions identified in Plaintiffs' motion.

B. Dr. Khandwala's Handling of Subjective Measures of Success Concerning Mesh and Nonmesh Procedures Should Be Addressed on Cross-Examination.

Plaintiffs take issue with Dr. Khandwala's comparison of two mesh hysteropexy[1] studies, yet—even if Plaintiff's unsupported recalculations of the data are true[2] —these are only two of many studies discussed by Dr. Khandwala supporting his opinions on success rates between mesh and nonmesh procedures. *See* Ex. B to Pls.' Mot. (Dkt. 2003-2), Khandwala Report at 8-17 (discussing the 2007 Hiltumen study (at 8), the Nieminen study (at 9), and the Altman study (at 10)). Despite the attention given in Plaintiffs' motion to the Lin study, they never asked Dr. Khandwala a single question about it or showed him their recalculated data at his deposition.

Similarly, Plaintiffs' arguments that Dr. Khandwala overly relied on objective measures of success and ignored subjective success metrics are misguided. *See* Pls.' Mem. (Dkt. 2004) at 4-7. Plaintiffs provide no support whatsoever—let alone scientific support—for their argument that an expert must give equal or greater weight to subjective measures of success over objective measures. Nor have they demonstrated how any of their criticisms have any bearing under *Daubert*. Even so, Plaintiffs' fundamental assertion that Dr. Khandwala "relied exclusively upon

[1] Hysteropexy is defined as the "fixation of a misplaced or abnormally moveable uterus." STEDMAN'S MEDICAL DICTIONARY 757 (25th ed. 1982).

[2] Plaintiffs have provided no data or documentation showing how their figures were calculated, let alone demonstrated the accuracy and reliability of their calculations and conclusions by an expert in the field. Further, if, as Plaintiffs contend, the Lin study is unreliable due to small sample size, so too are their recalculations of the data derived from the too-small sample size.

objective measurements of success" (*id*. at 5) is simply incorrect. Dr. Khandwala in fact addressed subjective outcomes throughout his report. *See, e.g*., Ex. B to Pls.' Mot. (Dkt. 2003-2), Khandwala Report at 8 (2007 Hiltunen study[3]), 9 (Nieminen study[4]), and 10 (Altman study[5]).

At bottom, Plaintiffs' critique of the Lin study, and criticisms of Dr. Khandwala's handling of subjective measures of success, are appropriately reserved for cross-examination. As previously determined by this Court, an expert's reasons for rejecting certain studies, and handling of alleged inconsistencies, go to the weight of the evidence, not its admissibility. *See Wilkerson v. Boston Scientific Corp*., No. 2:13-CV-04505, 2015 WL 2087048, at *10 (S.D. W. Va. May 5, 2015) ("Whether [the expert's] reasons for rejecting certain studies are accurate or whether [the expert] inconsistently applies these reasons to the literature are appropriate topics for cross-examination."); *Manpower, Inc. v. Ins. Co. of Pennsylvania*, 732 F.3d 796, 809 (7th Cir. 2013) (stating that whether the expert selected the best data set or relied on faulty information is a matter to be explored on cross-examination; it does not go to admissibility); *Kuhn v. Wyeth, Inc*., 686 F.3d 618, 632 (8th Cir. 2012) ("The studies' limitations may be presented to the jury.").

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[3] Hiltunen, et al. conducted a randomized study of 201 postmenopausal women with anterior prolapse. The study found that 38.5% of the women in the nonmesh group experienced recurrence at one year while 6.7% of the women in the mesh group experienced recurrence at one year. Ex. B to Pls.' Mot. (Dkt. 2003-2), Khandwala Report at 8.

[4] Nieminen, et al. conducted a randomized study in women with anterior wall prolapse. At three years, 13% of the women in the mesh group experienced recurrence while 41% of the women in the traditional repair group experienced recurrence. Ex. B to Pls.' Mot. (Dkt. 2003-2), Khandwala Report at 9.

[5] Altman, et al. conducted a randomized trial in women with cystoceles. At one year, anatomic and subjective success was found in 60.8% of the mesh group but in only 34.5% of the nonmesh group. Ex. B to Pls.' Mot. (Dkt. 2003-2), Khandwala Report at 10.

C. Dr. Khandwala's Prolift Opinions are Based on More Than His Own Clinical Study, and Include Bases This Court Has Already Deemed Reliable Under *Daubert*.

Despite the several reliable bases for Dr. Khandwala's safety and efficacy opinions established above, Plaintiffs inexplicably claim that his Prolift opinions are based "largely on his own four year study." Pls.' Mem. (Dkt. 2004) at 8. Dr. Khandwala's deposition testimony[6] unequivocally identifies several other bases for his opinions that Plaintiffs ignore. For example, he named the specific authors for each study upon which he relied, in addition to testifying as to his own surgical experience, and information learned at summit meetings. Ex. C to Pls.' Mot. (Dkt. 2003-3), 3/25/16 Khandwala Dep. Tr. 170:110-172:11. He relied not only upon his own clinical data, but also the "unbelievable results" after further follow-up, a review of the literature that "abounds with fantastic results," and the experiences of surgeons around the world with "phenomenal" success. *Id*. at 131:9-132:5.

Plaintiffs overemphasize the fact that Dr. Khandwala's Prolift study was not published. That study is only one among several that he relied upon, in addition to several other bases for his opinions. Even so, peer review is but one factor for the court to consider and even then it is not dispositive. *Eghnayem*, 57 F. Supp. 3d at 714. That Dr. Khandwala's study has not been published does not make his surgical results with Prolift unreliable despite their unpublished status. And a surgeon's own clinical experience need not be published for it to serve as a reliable basis for his opinions. Again, this Court has already established that surgical experience and (unpublished) literature suffice as reliable bases for safety and efficacy opinions. *Id.*; *Mathison*, 2015 WL 2124991, at *29; *Winebarger*, 2015 WL 1887222, at *7. Yet, Dr. Khandwala has

[6] Plaintiffs only cited to a small snippet of Dr. Khandwala's responses to their questions about the bases for his safety and efficacy opinions. *See* Pls.' Mem. (Dkt. 2004) at 8.

relied upon these things and more to support his opinions. Plaintiffs' nitpicks can be addressed on cross-examination, and their motion should be denied accordingly.

II. Plaintiffs' Motion Should Be Denied Because Dr. Khandwala Offers Qualified and Reliable Opinions Concerning the Prolift Devices' Biocompatibility and Physical Properties.

Dr. Khandwala has testified to what the literature, his own work, and his observations establish, namely that there is no visible contraction or degradation in the mesh he explants nor has he seen any clinical consequences. With respect to degradation, for example, he says he has not seen it and that is consistent with what plaintiffs' experts say, which is that it is only visible in a one micron layer seen through an electron microscope. And, like Dr. Khandwala, they have no evidence that Prolene degrades in a way that has clinical consequences. His testimony goes to the existence of clinical consequences, and the jury can certainly take into consideration that his opinion is based on what he has seen and read.

A. Dr. Khandwala is Qualified to Give Opinions Relating to Mesh Biocompatibility and its Physical Properties Such as Contraction.

Plaintiffs' claim that Dr. Khandwala must be an expert in fields such as biomaterials, biocompatibility, and pathology to qualify to testify on those subjects contradicts this Court's established precedent. A urogynecologist's "extensive experience with pelvic-floor disorders and the use of mesh to treat these disorders qualifies him to render opinions on [product design], notwithstanding his lack of expertise in the particular areas of product design or biomaterials." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D.W. Va. 2013) (finding Dr. Shull qualified, but excluding his design opinion on reliability grounds); *see also*, *Mathison*, 2015 WL 2124991, at *28 (finding Dr. Green qualified to opine on the physical properties of mesh) . Further, a physician's "experience removing polypropylene transvaginal mesh devices and performing

revision and excision procedures qualifies him" to give product design opinions. *Winebarger*, 2015 WL 1887222, at *6.

In *Mathison*, the plaintiffs sought to exclude the defendant's expert urologist from offering opinions relating to the physical properties of polypropylene, including shrinkage, contraction, and degradation, because the expert did not have pathology expertise. 2015 WL 2124991, at *28. The Court rejected the plaintiffs' argument, finding that the expert was qualified due to his experience performing thousands of sling procedures, and the literature cited throughout his expert report supporting his opinion that the mesh was safe and effective. *Id.*

Like the physicians in *Mathison*, *Winebarger*, and *In re C.R. Bard*, Dr. Khandwala has extensive experience treating women with pelvic-floor disorders using polypropylene mesh. He has implanted polypropylene in over 1,500 patients, and followed their care at regular intervals. Ex. C to Pls.' Mot. (Dkt. 2003-3), Khandwala 3/25/16 Dep. Tr. 99:4-14, 101:12-16. He has treated patients experiencing complications relating to pelvic floor procedures with and without mesh, including those of other surgeons. Ex. B to Pls.' Mot. (Dkt. 2003-2), Khandwala Report at 2-3. Accordingly, Dr. Khandwala is qualified to render opinions relating to the clinical aspects of product design, including mesh physical properties and its biocompatibility.[7]

[7] Plaintiffs' concern that Dr. Khandwala will offer new opinions not contained in his expert report is misplaced. Pls.' Mem. (Dkt. 2004) at 8-9. Dr. Khandwala discussed the physical properties and biocompatibility of the Prolift devices in his report. *See id.* at 11-12 (describing mesh structure, material components, absorption, durability, stiffness, reduction of dyspareunia), 14 (elasticity, reduced fibrotic reaction), 15-16 (mesh exposure, erosion), and 17 (mesh contraction)).

B. Dr. Khandwala's Mesh Contraction Opinions are Based on Reliable Methodology.

Dr. Khandwala's mesh contraction opinions are supported by both literature and his clinical experience, fitting squarely within the parameters established by this Court for admissibility. According to Dr. Khandwala, scientific data is lacking to support mesh contraction following mesh repair, or the contention that contraction of mesh causes pelvic pain. Ex. B to Pls.' Mot. (Dkt. 2003-2), Khandwala Report at 16. If clinically significant mesh contraction existed, it would cause a patient's vaginal length to shorten. *Id.* at 17. Yet, Dr. Khandwala published an article and has reviewed literature demonstrating that implanted polypropylene mesh does not cause vaginal shortening or contraction. Ex. C to Pls.' Mot. (Dkt. 2003-3), Khandwala 3/25/16 Dep. Tr. 89:9-20; Ex. B to Pls.' Mot. (Dkt. 2003-2), Khandwala Report at 16-17. In his clinical trial, he specifically looked for vaginal shortening, and it did not occur. Ex. C to Pls. Mot. (Dkt. 2003-3), Khandwala 3/25/16 Dep. Tr. 90:12-20.

He further testified that he has never seen mesh contraction even though he has treated patients for mesh-related complications. *Id*. at 114:17-118:4. And in multiple mesh removal surgeries, Dr. Khandwala observed that the mesh displays no evidence of contraction. *Id*. at 115:18-24. Because these opinions are supported by Dr. Khandwala's extensive clinical experience and his analysis of the scientific literature,[8] they are sufficiently reliable under *Daubert*. *Mathison*, 2015 WL 2124991 at *28.

[8] Dr. Khandwala cites to Handa VL, Zyczynski HM, Brubaker L, et al. *Sexual function before and after sacrocolpopexy for pelvic organ prolapse*. Am J Obstet Gynecol 2007;197:629.e1-6; Lowman JK, Jones AL, Woodman PJ, et al. *Does the Prolift system cause dyspareunia?* Am J Obstet Gynecol 2008; 199:707.e1-6; and Dietz HP, Erdmann M, Shek KL. *Mesh contraction: myth or reality?* Am J Obstet Gynecol 2011; 204(173):e1-4. Ex. B to Pls.' Mot. (Dkt. 2003-2), Khandwala Report at 19-23 (reference list).

Despite Dr. Khandwala's research and clinical experience in this area, Plaintiffs suggest that the basis for his opinion is that he simply "does not believe in" mesh contraction. Pls.' Mem. (Dkt. 2004) at 12. In so stating, Plaintiffs confuse his conclusion with his methodology. They overlook his study of the scientific literature, and diminish his experience from over 1,500 cases involving polypropylene, follow-up of these patients up to two years afterward, and the resulting lack of clinical evidence of contraction or degradation. Ex. C to Pls.' Mot. (Dkt. 2003-3), Khandwala 3/25/16 Dep. Tr. 90:12-20, 99:4-14, 101:5-16, 114:17-118:4. Plaintiffs simply disagree with his conclusion resulting from the methodology he employed as an expert urogynecologist studying this issue. This disagreement should be addressed on cross-examination; it is not a basis for exclusion. *See Wilkerson*, 2015 WL 2087048, at *10; *see also Daubert*, 509 U.S. at 596; *Manpower, Inc.*, 732 F.3d at 809.

C. Plaintiffs Take Dr. Khandwala's Comments on Mesh Porosity and Stiffness Out of Context.

Plaintiffs seek to exclude Dr. Khandwala's "opinions" regarding mesh porosity and stiffness, but mischaracterize the basis under which he provided this information in his report. Dr. Khandwala is not offering opinions specific to mesh porosity and stiffness, particularly from a biomaterials perspective. Nor does he seek to establish definitive measurements for these parameters or explain the biomechanical theories underlying them. His comments on these mesh properties were provided to support his opinions about the important physical properties of the devices and their differences *from an implanting surgeon's perspective*. *See* Ex. B to Pls.' Mot. (Dkt. 2003-2), Khandwala Report at 11-12. He further explained that physicians made the switch

from Prolift to Prolift+M because of "potential"[9] advantages, including preserving lateral structural integrity, and improved longitudinal integrity, which could lead to a positive impact on sexual function (dyspareunia). Ex. C to Pls.' Mot. (Dkt. 2003-3), 3/25/16 Dep. Tr. 123:15-124:18. This information is helpful to the jury to understand what physical mesh properties matter to surgeons and why. A biomaterials expert cannot help the jury understand the surgeon's perspective in this manner. Accordingly, Plaintiffs' motion to exclude Dr. Khandwala's comments on mesh porosity and stiffness should be denied. *See In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig*., No. 2:12-CV-4301, 2014 WL 186872, at *20 (S.D.W. Va. Jan. 15, 2014) (quoting *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989) ("One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion.").

D. Dr. Khandwala Will Not Offer IFU or Degradation Opinions.

Plaintiffs correctly note that Dr. Khandwala did not specifically offer opinions concerning the IFU or degradation in his expert report. Plaintiffs did not object to Dr. Khandwala offering these opinions at his deposition, and they proceeded to question him at length about them. Plaintiffs have experienced no prejudice as a result of Dr. Khandwala offering his opinions at deposition rather than in his expert report. Out of respect for the Court's prior rulings concerning expert opinions not contained in the expert's report, however, Ethicon will not offer Dr. Khandwala for opinions regarding the IFU or degradation.

[9] Plaintiffs' criticism that lateral and longitudinal stiffness is "hypothetical" and "conjecture" misses the point. Pls.' Mem. (Dkt. 2004) at 16-17. Dr. Khandwala does not opine that these effects actually occur or that he has proven they occur. Rather, he simply explains the importance of these potential benefits to a surgeon transitioning from Prolift to Prolift+M. Ex. C to Pls.' Mot. (Dkt. 2003-3), 3/25/16 Dep. Tr. 123:15-124:18.

CONCLUSION

For the foregoing reasons, Ethicon respectfully requests that Plaintiffs' motion be denied in its entirety.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on May 9, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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